

EXHIBIT G

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION
4
5 IN RE: ETHICON, INC.,) Master File No.
6 PELVIC REPAIR SYSTEM) 2:12-MD-02327
7 PRODUCTS LIABILITY)
8 LITIGATION) MDL 2327
9)
10) JOSEPH R. GOODWIN
11) U.S. DISTRICT JUDGE
12 THIS DOCUMENT RELATES TO)
13 THE FOLLOWING CASES IN)
14 WAVE 1 OF MDL 200:) Civil Action Number
15) 2:12-cv-00899
16 Daphne Barker, et al. v.)
17 Ethicon, Inc., et al.)
18)
19)

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 EXPERT WITNESS TESTIMONY OF
 KIMBERLY H. ALLISON, M.D.
 (Pages 1 - 64)
 Held at the Stanford Park Hotel
 100 El Camino Real, Menlo Park, California
 Friday, March 18, 2016, 8:45 a.m.
 - - - -
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Kimberly H. Allison, M.D.

Page 2		Page 4	
1	APPEARANCES	1	Exhibit 9B Photograph 12
2		2	Exhibit 9C Photograph 12
3	For the Plaintiffs:	3	Exhibit 9D Photograph 12
4	Beasley Allen Crow Methvin Portis & Miles, P.C.	4	Exhibit 9E Photograph 12
5	218 Commerce Street	5	Exhibit 9F Photograph 12
6	Montgomery, Alabama 36104	6	Exhibit 10 Surgical Pathology Report, 12
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10		9	Midurethral Sling Mesh, Audra
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		25	
Page 3		Page 5	
1	INDEX OF EXAMINATIONS	1	KIMBERLY H. ALLISON, M.D.,
2		2	called as a witness by the Defendants herein, being
3	EXAMINATIONS PAGE	3	first duly sworn by the Certified Shorthand Reporter
4	MR. VOUDOURIS 6	4	was thereupon examined and testified as is
5	MS. O'DELL 57	5	hereinafter set forth.
6	MR. VOUDOURIS 58	6	MR. VOUDOURIS: Let the record reflect
7		7	we're here to cross-examine Dr. Allison on her
8		8	opinions in the Barker case, but by doing so, we're
9		9	not going to waive any right we have to strike her
10	INDEX OF EXHIBITS	10	supplemental report of those opinions based on their
11	NO. DESCRIPTION PAGE	11	untimely production.
12	Exhibit 1 Amended Notice of Deposition of Kimberly H. Allison, M.D. 6	12	MS. O'DELL: For the record, the report in
13		13	this matter was produced after February 1st, which
14	Exhibit 2 Rule 26 Expert Report of Kimberly H. Allison, M.D. 7	14	is the deadline set by the Court because
15	Exhibit 3 Curriculum Vitae of Kimberly H. Allison, M.D. 7	15	Ms. Barker's surgery occurred after the deadline and
16		16	it would have been impossible to comply with the
17	Exhibit 4 Facts or Data Considered in Forming Opinions 8	17	Court's scheduling order.
18	Exhibit 5 Exhibit C, Updated 3/16/2016, spreadsheet 9	18	And so on that basis --
19		19	MR. VOUDOURIS: Counsel, I believe --
20	Exhibit 6 Expert Report of Teri Longacre, M.D. 10	20	MS. O'DELL: -- I'll oppose your motion.
21	Exhibit 7 Expert Report of Hannes Vogel, M.D. 11	21	MR. VOUDOURIS: I believe you produced her
22		22	supplemental report of materials on March 16th; is
23	Exhibit 8 Supplemental Rule 26 Expert Report of Kimberly H. Allison, M.D. 11	23	that correct?
24		24	MS. O'DELL: That's correct. You will
25	Exhibit 9A Photograph 12	25	have full opportunity to examine her on the report

<p style="text-align: right;">Page 6</p> <p>1 today.</p> <p>2 EXAMINATION</p> <p>3 BY MR. VOUDOURIS:</p> <p>4 Q. Dr. Allison, good morning.</p> <p>5 A. Good morning.</p> <p>6 Q. Maybe we can go through some clerical</p> <p>7 housecleaning before we start asking some further</p> <p>8 questions. I'm going to hand you what we've marked</p> <p>9 as Exhibit 1.</p> <p>10 Can you identify that, please?</p> <p>11 A. This is the notice of deposition.</p> <p>12 (Whereupon, Exhibit 1 was marked for</p> <p>13 identification.)</p> <p>14 BY MR. VOUDOURIS:</p> <p>15 Q. And you've seen that document before?</p> <p>16 A. Yes.</p> <p>17 MR. VOUDOURIS: And, Counsel, regarding</p> <p>18 Schedule A, do we have agreement that she has</p> <p>19 produced the documents or materials requested in</p> <p>20 Schedule A, although I know you did file objections,</p> <p>21 correct?</p> <p>22 MS. O'DELL: They are produced consistent</p> <p>23 with her -- excuse me, consistent with the</p> <p>24 objections and responses involved in this case. I</p> <p>25 would give to you, Peter, a jump drive. I think I</p>	<p style="text-align: right;">Page 8</p> <p>1 identification.)</p> <p>2 BY MR. VOUDOURIS:</p> <p>3 Q. Is it current?</p> <p>4 A. Yes.</p> <p>5 Q. Any additions or deletions you would like</p> <p>6 to make?</p> <p>7 A. No.</p> <p>8 Q. Doctor, I'm going to hand you what we have</p> <p>9 marked as Exhibit 4. Can you identify that?</p> <p>10 A. These are my literature lists.</p> <p>11 (Whereupon, Exhibit 4 was marked for</p> <p>12 identification.)</p> <p>13 BY MR. VOUDOURIS:</p> <p>14 Q. Your reliance list?</p> <p>15 A. Reliance list.</p> <p>16 Q. There is also some medical records that</p> <p>17 are listed in the back.</p> <p>18 A. Yes.</p> <p>19 Q. And you have additional medical records</p> <p>20 for Ms. Barker; is that correct?</p> <p>21 MS. O'DELL: Object to the form. Did you</p> <p>22 say additional medical records?</p> <p>23 THE WITNESS: Beyond this list, let's see.</p> <p>24 BY MR. VOUDOURIS:</p> <p>25 Q. What I'm getting at is you -- in our other</p>
<p style="text-align: right;">Page 7</p> <p>1 gave it to you yesterday.</p> <p>2 MR. VOUDOURIS: I don't believe so. You</p> <p>3 showed it to me.</p> <p>4 MS. O'DELL: Yes, and I will give it to</p> <p>5 you. Giving you that jump drive will ensure that</p> <p>6 everything that is consistent with our objections</p> <p>7 and responses have been produced to you during the</p> <p>8 depositions yesterday and today.</p> <p>9 BY MR. VOUDOURIS:</p> <p>10 Q. Dr. Allison, I'll hand you what we have</p> <p>11 marked as Exhibit 2. Could you identify that for</p> <p>12 the record, please?</p> <p>13 A. This is my expert report.</p> <p>14 (Whereupon, Exhibit 2 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. VOUDOURIS:</p> <p>17 Q. Is that your first expert report regarding</p> <p>18 this case?</p> <p>19 A. Yes, my supplemental report --</p> <p>20 Q. We'll get there.</p> <p>21 A. -- came subsequently.</p> <p>22 Q. Can you identify for us what we have</p> <p>23 marked as Exhibit 3?</p> <p>24 A. This is my CV.</p> <p>25 (Whereupon, Exhibit 3 was marked for</p>	<p style="text-align: right;">Page 9</p> <p>1 cases, you had a document very similar to this, but</p> <p>2 it did not list out Ms. Barker's medical records</p> <p>3 concerning her revision or her excision, so --</p> <p>4 A. Yes.</p> <p>5 Q. -- that's what I'm asking.</p> <p>6 A. They were likely not available at the</p> <p>7 time.</p> <p>8 Q. Do you know when you got the medical</p> <p>9 records in Barker that resulted in your</p> <p>10 supplementation of your report?</p> <p>11 A. Medical records, I got the slides in the</p> <p>12 beginning of March. So I was reviewing medical</p> <p>13 records and the pathology at that time. I have been</p> <p>14 away at a meeting for the last week.</p> <p>15 Q. Up in Seattle, right?</p> <p>16 A. Yes.</p> <p>17 Q. Was Dr. Longacre at the same meeting?</p> <p>18 A. Yes, she was.</p> <p>19 Q. I'm going to hand you what we -- and I'm</p> <p>20 sorry, did you get the pathology slides and the</p> <p>21 medical records at the same time, at the beginning</p> <p>22 of March?</p> <p>23 A. I believe so.</p> <p>24 Q. I'll hand you what is marked as Exhibit 5.</p> <p>25 (Whereupon, Exhibit 5 was marked for</p>

<p style="text-align: right;">Page 10</p> <p>1 identification.)</p> <p>2 BY MR. VOUDOURIS:</p> <p>3 Q. What is that?</p> <p>4 A. This is the spreadsheet that I used to</p> <p>5 summarize my findings.</p> <p>6 Q. And it now has a column filled in for</p> <p>7 Ms. Barker?</p> <p>8 A. Correct.</p> <p>9 Q. Whereas the similar sheets that we talked</p> <p>10 about yesterday did not have any information filled</p> <p>11 in for Ms. Barker?</p> <p>12 A. Correct.</p> <p>13 Q. Handing you what is marked as Exhibit 6.</p> <p>14 (Whereupon, Exhibit 6 was marked for</p> <p>15 identification.)</p> <p>16 BY MR. VOUDOURIS:</p> <p>17 Q. Can you identify that, please?</p> <p>18 A. This is the expert report of Dr. Teri</p> <p>19 Longacre.</p> <p>20 Q. And we discussed in detail the contents of</p> <p>21 that report yesterday, correct?</p> <p>22 A. Yes, we did.</p> <p>23 Q. And for the record, Dr. Longacre is whom?</p> <p>24 A. She is a GYN pathologist at Stanford.</p> <p>25 She's a professor of pathology.</p>	<p style="text-align: right;">Page 12</p> <p>1 BY MR. VOUDOURIS:</p> <p>2 Q. And that's dated when?</p> <p>3 A. It's dated February -- what is the date?</p> <p>4 Q. The last page.</p> <p>5 A. 16th of March.</p> <p>6 Q. Handing you what is marked as Exhibits 9A</p> <p>7 through 9F.</p> <p>8 (Whereupon, Exhibit 9A, Exhibit 9B,</p> <p>9 Exhibit 9C, Exhibit 9D, Exhibit 9E, and Exhibit 9F</p> <p>10 were marked for identification.)</p> <p>11 BY MR. VOUDOURIS:</p> <p>12 Q. Can you identify those, please?</p> <p>13 A. These are the representative photographs I</p> <p>14 took of the pathology slides on Ms. Barker.</p> <p>15 Q. Were the slides already given to you</p> <p>16 stained?</p> <p>17 A. Yes, they were.</p> <p>18 Q. Did you do anything to the slides other</p> <p>19 than take photographs?</p> <p>20 A. No, I did not.</p> <p>21 MS. O'DELL: Other than review them.</p> <p>22 MR. VOUDOURIS: Exhibit 10.</p> <p>23 (Whereupon, Exhibit 10 was marked for</p> <p>24 identification.)</p> <p>25 THE WITNESS: This is the pathology report</p>
<p style="text-align: right;">Page 11</p> <p>1 Q. Is she head of the GYN department at</p> <p>2 Stanford?</p> <p>3 A. There is no GYN department currently.</p> <p>4 Q. She's a program director of the breast/GYN</p> <p>5 residency training program, correct?</p> <p>6 A. Yes, which I co-direct.</p> <p>7 Q. Handing you what is marked as Exhibit 7.</p> <p>8 (Whereupon, Exhibit 7 was marked for</p> <p>9 identification.)</p> <p>10 BY MR. VOUDOURIS:</p> <p>11 Q. Can you identify that, please?</p> <p>12 A. This is the expert report of Dr. Hannes</p> <p>13 Vogel.</p> <p>14 Q. And Dr. Vogel is who?</p> <p>15 A. He's a neuropathologist at Stanford.</p> <p>16 Q. And do you know Dr. Vogel?</p> <p>17 A. Yes, he is one of my colleagues.</p> <p>18 Q. Well respected in his field?</p> <p>19 A. Yes.</p> <p>20 Q. Exhibit 8.</p> <p>21 (Whereupon, Exhibit 8 was marked for</p> <p>22 identification.)</p> <p>23 THE WITNESS: This is my supplemental</p> <p>24 report on the pathology that became available to me</p> <p>25 after my initial report was produced.</p>	<p style="text-align: right;">Page 13</p> <p>1 from Ms. Barker's February 12, 2006, procedure.</p> <p>2 BY MR. VOUDOURIS:</p> <p>3 Q. And does that correspond with the slides</p> <p>4 that you reviewed?</p> <p>5 A. It is the gross specimen -- gross</p> <p>6 exam-only component of that. They did not do a</p> <p>7 microscopic examination.</p> <p>8 Q. Do you know what the volume of GYN path</p> <p>9 sign-outs was in 2015 at Stanford?</p> <p>10 A. No, I do not. I don't know the volume of</p> <p>11 breast pathology either. I don't know the volume.</p> <p>12 I know our overall volume. We hit -- how many --</p> <p>13 Q. 50?</p> <p>14 A. -- thousands of specimens.</p> <p>15 Q. If you can, can you get Dr. Longacre's</p> <p>16 report in front of you?</p> <p>17 A. Okay.</p> <p>18 Q. Has plaintiffs' counsel told you, informed</p> <p>19 you that Dr. Longacre is going to be an expert in</p> <p>20 this case for the defense?</p> <p>21 A. I am aware of that now.</p> <p>22 Q. When did you become aware of that?</p> <p>23 A. Last week.</p> <p>24 Q. Can you go to page two of Dr. Longacre's</p> <p>25 report? That top paragraph, there is a sentence</p>

<p style="text-align: right;">Page 14</p> <p>1 that starts "Because," about six or seven lines 2 down. 3 A. Page two? 4 Q. Yes. 5 A. Okay. 6 Q. Do you see that? 7 A. Yes. 8 Q. Can you read that sentence, please? 9 A. "Because of my expertise in gynecologic 10 pathology, I was invited to become a member of the 11 American Board of Pathology Test Committee in order 12 to provide gynecologic pathology questions for the 13 certification exam for pathology residents as well 14 as the maintenance of certification exam for 15 practicing pathologists." 16 Q. Okay. What does that mean? 17 A. It means she helps write questions for the 18 boards. 19 Q. Helps write GYN pathology questions for 20 the board exam, correct? 21 A. Correct. 22 Q. Do you do that? 23 A. No, I do not. 24 Q. Let's go to Dr. Vogel's report. You can 25 also go to page two of that report. Bottom</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. So when it comes to interpretation of 2 nerves and scar tissue surrounding mesh and whether 3 there is a generation of pain sensation, who is more 4 qualified to answer those questions, you or 5 Dr. Vogel? 6 A. Dr. Vogel is an expert in neuropathology. 7 He does a lot of work with nerve, muscle and brain 8 tumors. I am a pathologist who was trained in 9 general pathology and specialized in GYN and breast 10 pathology. I have been in practice for ten years 11 and I -- it's -- evaluating whether nerves are 12 present in scar tissue is not an expert-level 13 diagnosis. Identification of nerves and scar tissue 14 is pretty basic. 15 Q. All right. Listen to my question again, 16 please. When it comes to the interpretation of 17 nerves in scar tissue or adjacent to scar tissue, 18 and whether there is a generation of pain sensation, 19 who is more qualified to answer those questions, 20 Dr. Vogel or you? 21 A. Dr. Vogel has more experience than I do in 22 his career, and I think the identification of nerves 23 in scar tissue and linking them to clinical symptoms 24 like pain is something that both of us are qualified 25 to do.</p>
<p style="text-align: right;">Page 15</p> <p>1 paragraph that starts with, "I held." Can you read 2 that, please? 3 A. "I held a position of responsibility for 4 writing test questions in neuropathology, including 5 nerve and muscle pathology, on the American 6 Association of Neurologists Committee For Preparing 7 the Residency In-Service Training Examination used 8 in every accredited neuropathology training program 9 in the United States between 2005 and 2012." 10 Q. And the next sentence, please? 11 A. "I have recently provided test questions 12 in the field of nerve and muscle pathology for the 13 autologous in-service examination of neuropathology 14 fellows in the U.S. administered by the American 15 Association of Neuropathologists." 16 Q. And what does that basically mean? 17 A. He writes test questions. 18 Q. For the board exam? 19 A. For the -- one is the residency in-service 20 training exam so it's a practice board exam. And 21 the same thing, they are not board exams. 22 Q. Have you ever been asked to do -- to write 23 questions, board exam questions, for these entities 24 like Dr. Vogel? 25 A. No.</p>	<p style="text-align: right;">Page 17</p> <p>1 Q. And what makes you qualified to do that? 2 A. It's part of general pathology. 3 Q. Yesterday we had an opportunity to go 4 through Dr. Longacre's report line by line and had 5 you indicate where you disagreed with Dr. Longacre's 6 opinions. So I would like to do the same with 7 Dr. Vogel, please. Take your time. 8 A. I have not seen this report before. So it 9 could take some time. 10 Q. I want you to read from page one to the 11 top of page 15, including that last paragraph. And 12 I want you to jump, when you are finished with that, 13 to his conclusion that starts on page 19. 14 MS. O'DELL: Dr. Allison, if there are 15 other aspects of the report that you need to read to 16 answer Peter's question, you are welcome to do that. 17 THE WITNESS: Okay. 18 BY MR. VOUDOURIS: 19 Q. What page are you on? 20 A. Seven. 21 Q. Let me know when you get to -- when you 22 finish before you get to response to plaintiffs' 23 expert. 24 A. Okay. So I'm now at response to 25 plaintiffs' expert. I don't disagree with anything</p>

<p style="text-align: right;">Page 18</p> <p>1 he said so far.</p> <p>2 Q. All right. Now let's go on to the next</p> <p>3 paragraph, response to plaintiffs' expert.</p> <p>4 A. So he is mainly discussing Dr. Iakovlev.</p> <p>5 Q. Correct. Who you rely upon for many of</p> <p>6 your opinions in this case, correct?</p> <p>7 MS. O'DELL: Object to the form.</p> <p>8 THE WITNESS: I relied upon the literature</p> <p>9 that he has published as a pathologist who has</p> <p>10 looked at many of these questions about mesh.</p> <p>11 BY MR. VOUDOURIS:</p> <p>12 Q. So the answer to my question is yes?</p> <p>13 MS. O'DELL: Object to the form.</p> <p>14 THE WITNESS: Yes, but I may not have the</p> <p>15 exact same assessment on a case as Dr. Iakovlev.</p> <p>16 BY MR. VOUDOURIS:</p> <p>17 Q. Tell me when you get to response to</p> <p>18 Dr. Iakovlev's published medical literature.</p> <p>19 A. Okay. Okay. I'm now at response to</p> <p>20 Dr. Iakovlev's published medical literature.</p> <p>21 Q. Okay. So you have read the response to</p> <p>22 plaintiffs' expert which is on pages 7, 8, and 9,</p> <p>23 correct?</p> <p>24 A. Yes.</p> <p>25 Q. Any disagreements with what Dr. Vogel has</p>	<p style="text-align: right;">Page 20</p> <p>1 Dr. Iakovlev has not established anything that would</p> <p>2 enable other pathologists to predict which patients</p> <p>3 would experience pain based on nerve fiber</p> <p>4 densities."</p> <p>5 I have not argued that nerve fiber density</p> <p>6 is the only factor that I'm using in my analysis.</p> <p>7 Pathologists use many features to come to</p> <p>8 conclusions about linking clinical symptoms to</p> <p>9 pathology.</p> <p>10 Q. All right. Can you read the next section,</p> <p>11 please, response to Dr. Iakovlev's expert report?</p> <p>12 A. Response to Dr. Iakovlev's.</p> <p>13 Q. I apologize. I skipped a whole section.</p> <p>14 We're on page nine, right?</p> <p>15 A. Yes.</p> <p>16 Q. Response to Dr. Iakovlev's published</p> <p>17 medical literature. Which you have reviewed,</p> <p>18 correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you reviewed as part of your</p> <p>21 conclusions reached to a reasonable degree of</p> <p>22 medical certainty in this case, correct?</p> <p>23 A. Correct.</p> <p>24 Q. All right. So you and Dr. Vogel have read</p> <p>25 the same literature, correct?</p>
<p style="text-align: right;">Page 19</p> <p>1 written in this report?</p> <p>2 A. He's mainly discussing Dr. Iakovlev's</p> <p>3 interpretation of cases that -- and publications as</p> <p>4 well that look at the number of nerve fibers present</p> <p>5 and argues that they may not be significant and it's</p> <p>6 hard to link them to pain. I have reviewed cases</p> <p>7 and the constellation of findings, I think, are</p> <p>8 linked to the patient's pain.</p> <p>9 So -- which include the presence of nerves</p> <p>10 entrapped in the dense scar and the erosions that</p> <p>11 are formed and it's multifactorial. Pain isn't</p> <p>12 caused by a single factor, I think. But it all is</p> <p>13 linked to the mesh present in the cases that I have</p> <p>14 reviewed.</p> <p>15 So I really can't comment on what he's</p> <p>16 referring to in Dr. Iakovlev's report, which I don't</p> <p>17 have. And it just doesn't seem that relevant to my</p> <p>18 evaluation of the cases.</p> <p>19 Q. Dr. Allison, is there any sentence in this</p> <p>20 section of Dr. Vogel's report response to</p> <p>21 plaintiffs' expert that is incorrect?</p> <p>22 A. No, I mean, he is very specific in the</p> <p>23 sentences he's using. I don't disagree with the</p> <p>24 specific things that he is saying. "For example, as</p> <p>25 the case with his vaginal mesh analysis,</p>	<p style="text-align: right;">Page 21</p> <p>1 A. Some of it, yes.</p> <p>2 Q. All right. Please read this section that</p> <p>3 starts on page nine and goes to 13 and tell us any</p> <p>4 sentence in here that you disagree with.</p> <p>5 MS. O'DELL: Dr. Allison, if there are any</p> <p>6 references that are mentioned in Dr. Vogel's report</p> <p>7 that you need to see, I'm sure Peter can provide</p> <p>8 those to you.</p> <p>9 MR. VOUDOURIS: Let the record reflect</p> <p>10 that plaintiffs' counsel has opened up one of the</p> <p>11 binders and put it in front of Dr. Allison with an</p> <p>12 article by Blaivas.</p> <p>13 Q. Continue to read, please.</p> <p>14 A. And Iakovlev. So that section of his</p> <p>15 report really is quoting Dr. Iakovlev and mentioning</p> <p>16 studies and statistics that I don't disagree with</p> <p>17 because it's -- it's not relevant to my opinion.</p> <p>18 It's discussing Iakovlev's particular</p> <p>19 phrasing in his articles. I mean, the fact is that</p> <p>20 it is a known complication of mesh procedures to</p> <p>21 have chronic pain. That's in studies that Iakovlev</p> <p>22 has not authored.</p> <p>23 Erosions are also a known complication.</p> <p>24 Erosions can be painful as well.</p> <p>25 Q. Are you through?</p>

<p style="text-align: right;">Page 22</p> <p>1 A. And I don't disagree that, you know, we 2 can't tell what kind of receptors are on the nerves 3 present. Their presence alone is something that I 4 comment on in my report and link it all together to 5 the full picture of the patient who actually 6 presents with pain. 7 Q. Do you disagree with any sentence that 8 Dr. Vogel has in his report in the section response 9 to Dr. Iakovlev's published medical literature? 10 A. Some of the reason I disagree with, but I 11 can't pick out a sentence that I would say, oh, I 12 don't agree -- that's relevant to my case opinions. 13 Q. All right. The next section starts on 14 page 13 of Dr. Vogel's report, response to 15 Dr. Iakovlev's expert report, correct? 16 A. Correct. 17 Q. Could you read that, please, and tell us 18 if there is any sentence in this section that you 19 believe is incorrect? And you only have to read to 20 the top of page 15. 21 MS. O'DELL: I would object to this line 22 of inquiry because Dr. Allison has neither seen nor 23 relied on Dr. Iakovlev's report in rendering her 24 opinions in this case. So it's unfair to ask her to 25 read criticisms of a report that is not been made</p>	<p style="text-align: right;">Page 24</p> <p>1 to badger the witness. 2 MR. VOUDOURIS: Are you done with your 3 speaking objections? 4 MS. O'DELL: Probably not. But you may 5 talk now. 6 MR. VOUDOURIS: Thank you. 7 Q. Dr. Allison, is the first sentence of 8 Dr. Vogel's report response to Dr. Iakovlev's expert 9 report contained on page 13 incorrect? 10 A. I answered that question saying I would 11 remove the word "erroneous" from that sentence. 12 Q. Keep reading. 13 MS. O'DELL: I would renew my objection to 14 this line of questioning because Dr. Allison has 15 neither been provided nor has she reviewed nor has 16 she relied on Dr. Iakovlev's expert report that was 17 served in this case. 18 MR. VOUDOURIS: Counsel, you already made 19 that objection. It's duly noted. 20 THE WITNESS: So the end of page 14, 21 Dr. Vogel states, "Stated differently, Dr. Iakovlev 22 has not provided any criteria of any sort whereby an 23 independent and unbiased microscopist could make a 24 link between the presence of incidental nerve twigs 25 and the usual inflammation associated with implanted</p>
<p style="text-align: right;">Page 23</p> <p>1 available to her. 2 THE WITNESS: So the first sentence, you 3 know, that Dr. Iakovlev's expert report 4 recapitulates "the erroneous link between fibrosis 5 and/or inflammation with pain in a small percentage 6 of patients having undergone mesh explantation as 7 described above." 8 I mean, I think that that is a link that 9 has been appropriately documented in patients with 10 pain. 11 BY MR. VOUDOURIS: 12 Q. So are you saying that first sentence by 13 Dr. Vogel is incorrect? 14 A. I would not use the word "erroneous" in 15 that sentence. 16 Q. I'm sorry, my question was -- 17 MS. O'DELL: She answered your question, 18 no. 19 MR. VOUDOURIS: No, she didn't. 20 MS. O'DELL: Yes, she did. And she -- 21 MR. VOUDOURIS: So you're saying that the 22 first sentence -- 23 MS. O'DELL: I'm talking. I'm talking. 24 She answered your question and just because you 25 don't like the answer doesn't mean you are entitled</p>	<p style="text-align: right;">Page 25</p> <p>1 mesh and pain symptoms in a small minority of 2 patients reporting pain versus the significant 3 majority of symptom-free patients having undergone 4 synthetic sling implantation." 5 Again, I would reiterate my previous 6 comments that when you are -- when I'm evaluating a 7 patient presenting with pain, which can be 8 multifactorial, I am going to note things like the 9 presence of nerve fibers embedded in the dense 10 fibrosis and consider it more likely than not that 11 they may contribute. This is in a patient who is 12 presenting with pain. 13 Erosion also can contribute to pain. And 14 when a patient walks in the door presenting with a 15 symptom, whether it be pain or a mass, we don't look 16 at randomized controlled trials to evaluate that 17 patient. We evaluate that patient. 18 BY MR. VOUDOURIS: 19 Q. I don't want to cut you off. Are you 20 through? 21 A. Yes. 22 Q. Okay. So is Dr. Vogel's statement that 23 you just requoted incorrect? 24 A. It's a little more subtle answer than that 25 because he is being very specific in this sentence</p>

<p style="text-align: right;">Page 26</p> <p>1 saying that Dr. Iakovlev has not provided any 2 criteria of any sort. And I am telling you that 3 when I evaluate a case, I can't comment on what 4 Dr. Iakovlev is doing. I can comment on what I am 5 doing.</p> <p>6 I don't have access to this report. I 7 don't know what Dr. Iakovlev's opinions are on the 8 case. I have read some of his literature. So I 9 can't say that he is incorrect. I could say that I 10 disagree with the concept that we can never link a 11 patient's symptom to the pathology in cases like 12 this.</p> <p>13 Q. And your basis for that statement is?</p> <p>14 A. Evaluation of cases where patients are 15 presenting with specific symptoms and linking the 16 pathology findings with them on a case-by-case 17 basis.</p> <p>18 Q. In all the medical literature that you 19 have reviewed for your opinions in this case, which 20 is in Exhibit 3 -- I'm sorry, Exhibit 4, what 21 articles support the statement that you just made?</p> <p>22 A. That patients present with pain. You want 23 me to find articles that look at patient's 24 presenting with pain? That --</p> <p>25 Q. No, I'm sorry. And we can have the court</p>	<p style="text-align: right;">Page 28</p> <p>1 When a physician sees a patient in their 2 office, they are going to take a history and try to 3 figure out what is going on and what is causing 4 their symptoms. There are not randomized trials on 5 when to use a microscope or when to use a 6 stethoscope.</p> <p>7 Q. Are there any randomized trials that you 8 know of contained in your Exhibit 4 that link the 9 clinical symptom of pain to what is seen on vaginal 10 tissue surrounding mesh?</p> <p>11 A. The studies link the presence of pain and 12 erosions to the clinical presentation. Pathologists 13 were not involved in the randomized trials. We get 14 left out of a lot of studies.</p> <p>15 Q. Can you point to anything in Exhibit 4 16 that is a randomized trial or trial that has a 17 control that links a specific clinical symptom of 18 pain to what can be seen on a pathology slide of 19 vaginal tissue that contains mesh?</p> <p>20 A. No.</p> <p>21 Q. Can you go to the conclusion in 22 Dr. Vogel's report that starts on page 19?</p> <p>23 Are you finished?</p> <p>24 A. Yes.</p> <p>25 Q. Is any sentence in Dr. Vogel's conclusion</p>
<p style="text-align: right;">Page 27</p> <p>1 reporter read back your answer so you know exactly 2 what the question is. Please?</p> <p>3 (Whereupon, the reporter read the record 4 as follows:</p> <p>5 "Answer: Evaluation of cases where 6 patients are presenting with specific symptoms and 7 linking the pathology findings with them on a 8 case-by-case basis.")</p> <p>9 THE WITNESS: That's in general the 10 pathologist's job is to link the pathology findings 11 whenever possible with the symptoms the patient is 12 presenting with. There is not literature to tell me 13 what my job is.</p> <p>14 BY MR. VOUDOURIS:</p> <p>15 Q. Can you show us any literature in 16 Exhibit 4 that supports your opinion that you can 17 look at histology of vaginal tissue and link 18 specific symptoms, and I'm going to call pain the 19 specific symptoms, with what is found on a pathology 20 slide?</p> <p>21 A. Again, that's not the sort of thing that 22 you would put in a random -- in an article that -- 23 this is my job that I do every day. Someone 24 presents with a mass, I'm going to try to explain 25 the mass on pathology.</p>	<p style="text-align: right;">Page 29</p> <p>1 in this report incorrect?</p> <p>2 A. Dr. Iakovlev describes the pathologic 3 findings in patients that have had mesh removed and 4 for a variety of reasons, including pain. So I 5 disagree with the sentence that his methodology is 6 not accepted. These were peer-reviewed articles 7 that were published, so the scientific community did 8 accept them for publication.</p> <p>9 Q. Anything else that is incorrect in that 10 conclusion?</p> <p>11 A. I disagree that it's a normal -- well, it 12 may be part of the normal healing process. He 13 states, "Dr. Iakovlev's opinions are not supported 14 by the histology which shows the normal healing 15 process in the vicinity of an implanted mesh."</p> <p>16 So while some of that healing process may 17 be normal, so I don't disagree with that, the issue 18 is that those nerves are there in this disrupted 19 tissue which has a foreign material in it and that 20 has the potential to create pain by having a scarred 21 area have nerve entrapped in it and disrupt the 22 functionality of that area.</p> <p>23 Q. So you are saying that sentence by 24 Dr. Vogel is incorrect?</p> <p>25 MS. O'DELL: She answered your question.</p>

<p style="text-align: right;">Page 30</p> <p>1 THE WITNESS: I said I don't disagree that</p> <p>2 it may be part of the healing process. So I guess I</p> <p>3 don't disagree with that specific sentence, you</p> <p>4 know. Obviously we have slightly different</p> <p>5 opinions.</p> <p>6 BY MR. VOUDOURIS:</p> <p>7 Q. I don't think you have slightly different</p> <p>8 opinions, Dr. Allison. I think you have vastly</p> <p>9 different opinions than Dr. Longacre and Dr. Vogel.</p> <p>10 In Exhibit 4, which is your reliance list,</p> <p>11 is there any literature or randomized control study</p> <p>12 in there that compares the tissues surrounding</p> <p>13 midurethral slings in women who did not complain of</p> <p>14 pain versus women who did complain of pain?</p> <p>15 MS. O'DELL: Would you mind repeating the</p> <p>16 question, please?</p> <p>17 THE WITNESS: Yeah.</p> <p>18 (Whereupon, the reporter read the record</p> <p>19 as follows:</p> <p>20 "Question: In Exhibit 4, which is your</p> <p>21 reliance list, is there any literature or randomized</p> <p>22 control study in there that compares the tissues</p> <p>23 surrounding midurethral slings in women who did not</p> <p>24 complain of pain versus women who did complain of</p> <p>25 pain?")</p>	<p style="text-align: right;">Page 32</p> <p>1 regarded?</p> <p>2 A. Yes.</p> <p>3 Q. I know you mentioned the Hill paper as one</p> <p>4 of your references, but do you mention the Hill</p> <p>5 paper in your report itself?</p> <p>6 A. No.</p> <p>7 Q. Does Dr. Vogel mention the Hill paper in</p> <p>8 his report?</p> <p>9 A. I would have to look. I'm not sure.</p> <p>10 Would you like me to go through it?</p> <p>11 Q. Let me see if I can help you out. Page</p> <p>12 ten.</p> <p>13 A. Yes, he does.</p> <p>14 Q. And could you read the conclusion for us</p> <p>15 on the first page of the Hill paper?</p> <p>16 A. "Midurethral sling mesh excised for</p> <p>17 voiding dysfunction demonstrates elevated levels of</p> <p>18 inflammation compared to mesh that is excised for</p> <p>19 pain and/or exposure."</p> <p>20 Q. All right. Next sentence.</p> <p>21 A. "The vaginal tissue fibrosis and giant</p> <p>22 cell reaction are similar in patients who undergo</p> <p>23 mesh excision for voiding dysfunction and pain</p> <p>24 and/or mesh exposure."</p> <p>25 Q. Do you question those conclusions?</p>
<p style="text-align: right;">Page 31</p> <p>1 THE WITNESS: Yes. Is this on my reliance</p> <p>2 list?</p> <p>3 BY MR. VOUDOURIS:</p> <p>4 Q. Are you talking about the Hill study?</p> <p>5 A. Yes. So the Hill study addresses --</p> <p>6 Q. Hold on one second. I'm sorry. There is</p> <p>7 no -- I'm looking for a sticker. Are we on 11?</p> <p>8 (Whereupon, a brief discussion off the</p> <p>9 record.)</p> <p>10 (Whereupon, Exhibit 11 was marked for</p> <p>11 identification.)</p> <p>12 BY MR. VOUDOURIS:</p> <p>13 Q. Doctor, I'm handing you what we have</p> <p>14 marked as Exhibit 11. Can you identify that,</p> <p>15 please?</p> <p>16 A. This is a histopathology of excised</p> <p>17 midurethral sling mesh, which is an article by</p> <p>18 Dr. Hill.</p> <p>19 Q. And these physicians and these authors are</p> <p>20 from the Cleveland Clinic?</p> <p>21 A. Yes.</p> <p>22 Q. Is the Cleveland Clinic a well-respected</p> <p>23 medical institution in the United States?</p> <p>24 A. Yes.</p> <p>25 Q. Is their pathology department also highly</p>	<p style="text-align: right;">Page 33</p> <p>1 A. Well, this study tries to look at pain</p> <p>2 versus no pain and in different groups. But there</p> <p>3 is no control group of patients with absolutely no</p> <p>4 symptoms. So they are comparing voiding dysfunction</p> <p>5 without pain. They are calling that the control</p> <p>6 group.</p> <p>7 Q. Right. Sounds like a reasonable control,</p> <p>8 doesn't it?</p> <p>9 A. There is still -- I mean, the best control</p> <p>10 would be patients who don't have any dysfunction.</p> <p>11 Don't you agree?</p> <p>12 Q. I'm sorry. Sounds like a reasonable</p> <p>13 control?</p> <p>14 MS. O'DELL: Object to the form. Asked</p> <p>15 and answered.</p> <p>16 THE WITNESS: I would say a better control</p> <p>17 would be patients who don't have any symptoms.</p> <p>18 BY MR. VOUDOURIS:</p> <p>19 Q. I know. My question was, is that a</p> <p>20 reasonable control?</p> <p>21 MS. O'DELL: That was not your question.</p> <p>22 MR. VOUDOURIS: That's my question now.</p> <p>23 THE WITNESS: I would have preferred a</p> <p>24 different control group, but that's the one that</p> <p>25 we're working with in this study and you have to</p>

<p style="text-align: right;">Page 34</p> <p>1 draw your conclusions on the basis of what they used</p> <p>2 for their control group.</p> <p>3 BY MR. VOUDOURIS:</p> <p>4 Q. Is it a reasonable control?</p> <p>5 A. I have answered your question two times.</p> <p>6 MS. O'DELL: Yes, she has.</p> <p>7 BY MR. VOUDOURIS:</p> <p>8 Q. Is it a reasonable control?</p> <p>9 MS. O'DELL: You have no -- you are not</p> <p>10 compelled to give a different answer to the same</p> <p>11 question, Dr. Allison. If you have answered his</p> <p>12 question, you stand on your answer.</p> <p>13 MR. VOUDOURIS: Are you done with your</p> <p>14 speaking objection?</p> <p>15 MS. O'DELL: I'm done.</p> <p>16 THE WITNESS: I am not obligated to give a</p> <p>17 yes-or-no answer. So I gave you my answer.</p> <p>18 BY MR. VOUDOURIS:</p> <p>19 Q. Who says you are not obligated to give a</p> <p>20 yes-or-no answer, the judge?</p> <p>21 A. I thought I was allowed to speak freely</p> <p>22 about my opinions in this setting and explain my</p> <p>23 answers.</p> <p>24 Q. Who told you you are not allowed to give a</p> <p>25 yes-or-no answer?</p>	<p style="text-align: right;">Page 36</p> <p>1 MS. O'DELL: You don't have to raise your</p> <p>2 voice to badger the witness. You are clearly</p> <p>3 badgering the witness and it's improper. So let the</p> <p>4 record reflect that you have asked the same question</p> <p>5 five times. It's improper.</p> <p>6 MR. VOUDOURIS: And let the record reflect</p> <p>7 she hasn't answered it five times.</p> <p>8 MS. O'DELL: She has answered your</p> <p>9 question.</p> <p>10 MR. VOUDOURIS: One more time,</p> <p>11 Dr. Allison.</p> <p>12 Q. The exhibit that you have in front of you,</p> <p>13 which is the Hill paper marked as Defendants'</p> <p>14 Exhibit 11, is that a reasonable control, yes or no?</p> <p>15 A. It's the control group that they had and</p> <p>16 you have to draw your conclusions on the basis of it</p> <p>17 in the context of this study. They thought it was a</p> <p>18 reasonable control group. They published the study.</p> <p>19 I would have preferred a different control group.</p> <p>20 That is my answer.</p> <p>21 Q. So you can't comment one way or another</p> <p>22 whether it was a reasonable control?</p> <p>23 A. I just did comment whether it was</p> <p>24 reasonable or not.</p> <p>25 Q. So it is?</p>
<p style="text-align: right;">Page 35</p> <p>1 A. I was under the assumption that I wasn't</p> <p>2 forced into a yes-or-no response, but maybe I'm not</p> <p>3 accurate in that assumption.</p> <p>4 MS. O'DELL: You may answer the questions</p> <p>5 in any fashion you want to, Dr. Allison. And you</p> <p>6 can disregard the representations being made by</p> <p>7 counsel for Ethicon.</p> <p>8 MR. VOUDOURIS: Speaking objection</p> <p>9 number seven.</p> <p>10 Q. Dr. Allison, in the Hill paper that you</p> <p>11 have in front of you that we have marked as</p> <p>12 Defendants' Exhibit 11, is that a reasonable</p> <p>13 control?</p> <p>14 MS. O'DELL: Object to the form. Asked</p> <p>15 and answered.</p> <p>16 THE WITNESS: I believe I answered your</p> <p>17 question.</p> <p>18 BY MR. VOUDOURIS:</p> <p>19 Q. Then do it again. Please answer my</p> <p>20 question.</p> <p>21 MS. O'DELL: Stop badgering the witness,</p> <p>22 Counsel. She's answered your question. You may not</p> <p>23 like the answer, but she's answered it.</p> <p>24 MR. VOUDOURIS: There is no badgering</p> <p>25 going on. Did I raise my voice?</p>	<p style="text-align: right;">Page 37</p> <p>1 A. It's reasonable in the context of their</p> <p>2 study.</p> <p>3 MS. O'DELL: We have been going about an</p> <p>4 hour. Let's go off the record.</p> <p>5 MR. VOUDOURIS: What is our time?</p> <p>6 (Whereupon, a brief recess was taken.)</p> <p>7 BY MR. VOUDOURIS:</p> <p>8 Q. Dr. Allison, in reaching your opinions in</p> <p>9 any of the three Ethicon cases that we have been</p> <p>10 discussing over the last two days, did you rely on</p> <p>11 any of Dr. Iakovlev's expert reports?</p> <p>12 A. No.</p> <p>13 Q. In rendering your opinions or reaching</p> <p>14 your opinions in these three Ethicon cases, did you</p> <p>15 rely on any of Dr. Iakovlev's sworn testimony?</p> <p>16 A. No.</p> <p>17 Q. If we can, let's go to the</p> <p>18 photomicrographs that you took. And again, if you</p> <p>19 don't mind, I'm going to come over your shoulder</p> <p>20 again and I'm going to give you a blue pen.</p> <p>21 MS. O'DELL: Why don't you just stay right</p> <p>22 there.</p> <p>23 MR. VOUDOURIS: I'll stand up. How is</p> <p>24 that?</p> <p>25 THE WITNESS: Okay. So you want me to --</p>

<p style="text-align: right;">Page 38</p> <p>1 BY MR. VOUDOURIS:</p> <p>2 Q. Hold on one second.</p> <p>3 A. -- use a different set of -- we want an</p> <p>4 exhibit or --</p> <p>5 Q. Yes, you want the ones that have the</p> <p>6 exhibit stickers on them. There you go.</p> <p>7 Identify for the record, please, the first</p> <p>8 photograph.</p> <p>9 A. First photograph is a low-power image of</p> <p>10 the tissue removed for microscopic examination from</p> <p>11 the February 12, 2006, surgery to remove the</p> <p>12 patient's TVT device.</p> <p>13 Q. And do you know exactly where this tissue</p> <p>14 was taken from?</p> <p>15 MS. O'DELL: Can I just -- excuse me,</p> <p>16 Counsel.</p> <p>17 I'm sorry, I think you said 2006. Did you</p> <p>18 mean --</p> <p>19 THE WITNESS: I meant 2016, yes. Thank</p> <p>20 you.</p> <p>21 MS. O'DELL: I'm sorry. Go ahead.</p> <p>22 BY MR. VOUDOURIS:</p> <p>23 Q. I forgot my question.</p> <p>24 (Whereupon, the reporter read the record</p> <p>25 as follows:</p>	<p style="text-align: right;">Page 40</p> <p>1 A. Oh, it's all sort of one in the same.</p> <p>2 Q. So you equate dense fibrosis with scar?</p> <p>3 A. Yes.</p> <p>4 Q. Any other findings that you're going to</p> <p>5 tell the jury that is of significance to this</p> <p>6 microphotograph 9A?</p> <p>7 A. Presence of the mesh fibers and the dense</p> <p>8 fibrosis scar is the main findings demonstrated in</p> <p>9 this image.</p> <p>10 Q. Okay. I understand they are the main</p> <p>11 findings in this image, but I need to know what you</p> <p>12 are going to tell the jury about the significance of</p> <p>13 this slide. Or have we covered it all?</p> <p>14 A. I think we have covered it.</p> <p>15 Q. All right.</p> <p>16 A. So Exhibit 9B has a higher power image,</p> <p>17 representative image, of the area of the fibrosis</p> <p>18 and the scar which is encasing the mesh fibers.</p> <p>19 Again, I'll circle the entire area and label it.</p> <p>20 And there is minimal chronic inflammation</p> <p>21 in this image.</p> <p>22 Q. Can you circle the minimal chronic</p> <p>23 inflammation, please?</p> <p>24 A. (Witness complies.)</p> <p>25 Q. And can you somehow label that? Thank</p>
<p style="text-align: right;">Page 39</p> <p>1 "Question: And do you know exactly where</p> <p>2 this tissue was taken from?")</p> <p>3 THE WITNESS: It was taken from the three</p> <p>4 fragments of cauterized pink, tan, red, brown soft</p> <p>5 tissue that contained the mesh.</p> <p>6 BY MR. VOUDOURIS:</p> <p>7 Q. Does cauterized mean heat was used to take</p> <p>8 this material out of the body?</p> <p>9 A. Potentially. I couldn't comment on that.</p> <p>10 Q. Can you please explain to us what you find</p> <p>11 of significance on 9A that you are going to tell the</p> <p>12 jury is related to Ms. Barker's mesh?</p> <p>13 A. So she has findings typical of the cases</p> <p>14 that I have examined in patients that are</p> <p>15 complaining of symptoms related to their mesh. So</p> <p>16 she's got dense fibrosis and scarring surrounding</p> <p>17 the mesh fibers which are these holes here, one of</p> <p>18 which has retained some blue suture or mesh</p> <p>19 material.</p> <p>20 Q. Can you circle for us dense fibrosis?</p> <p>21 A. (Witness complies.)</p> <p>22 Q. I think Ms. O'Dell has a pen that has more</p> <p>23 ink in it.</p> <p>24 A. (Witness complies.)</p> <p>25 Q. And can you mark for us the scar?</p>	<p style="text-align: right;">Page 41</p> <p>1 you.</p> <p>2 A. And then there's also --</p> <p>3 Q. I'm sorry to interrupt you.</p> <p>4 A. You want me to label each one?</p> <p>5 Q. Yes.</p> <p>6 A. Okay. In addition to the spaces formed by</p> <p>7 mesh fibers, there is one mesh fiber present that</p> <p>8 was retained in the tissue and then there is the</p> <p>9 so-called tree barking that I take as evidence under</p> <p>10 the light microscope of degradation of the mesh</p> <p>11 fiber that's present in one of these spaces. I'll</p> <p>12 label that "tree barking."</p> <p>13 Q. Did you measure that tree barking?</p> <p>14 A. No.</p> <p>15 Q. Do you have any idea how -- the depth of</p> <p>16 that tree barking?</p> <p>17 A. No, I didn't measure it.</p> <p>18 Q. Anything else of significance that you are</p> <p>19 going to tell the jury about Exhibit 9B?</p> <p>20 A. No.</p> <p>21 Q. 9C?</p> <p>22 A. 9C is just a higher power image so you can</p> <p>23 see that tree barking in the mesh fiber region. You</p> <p>24 can see it around a mesh fiber that is still intact</p> <p>25 here a little bit better. I'll try to highlight</p>

<p style="text-align: right;">Page 42</p> <p>1 this. You can see it's present around the mesh</p> <p>2 fiber and then in most of these spaces, the main</p> <p>3 component of the mesh fibers come out with tissue</p> <p>4 processing, but it's left behind this rind or rim of</p> <p>5 material.</p> <p>6 Q. That you believe is tree barking?</p> <p>7 A. Yes.</p> <p>8 Q. That represents degraded polypropylene</p> <p>9 in vivo?</p> <p>10 A. That's what has been described and I see</p> <p>11 evidence of that under the microscope in this case.</p> <p>12 Q. Anything else?</p> <p>13 A. I could circle some of the chronic</p> <p>14 inflammation, although it's a bit crushed in these</p> <p>15 particular fields. I'll write "crushed."</p> <p>16 Q. And why is it crushed?</p> <p>17 A. It looks like it's just crushed from</p> <p>18 compression of the tissue, maybe it was being pulled</p> <p>19 out. The lymphocytes are fragile and they can crush</p> <p>20 easily. So you can see the rest of the tissue is</p> <p>21 not that crushed.</p> <p>22 Q. Do you see any blood vessels?</p> <p>23 A. I see some red blood cells, but I think</p> <p>24 they are probably procedure related. So not in a</p> <p>25 blood vessel, per se. So I don't see good</p>	<p style="text-align: right;">Page 44</p> <p>1 this blue is collagen-related tissue, so...</p> <p>2 Q. Can you indicate that, please, on there?</p> <p>3 A. It highlights the scar. Red blood cells</p> <p>4 are stained in red.</p> <p>5 Q. So there are blood vessels in that scar?</p> <p>6 A. I can't definitively say there are blood</p> <p>7 vessels in there based on this.</p> <p>8 Q. Do you know who stained that slide?</p> <p>9 A. No, it was provided to me.</p> <p>10 Q. Did you request that particular stain?</p> <p>11 A. No.</p> <p>12 Q. Anything else you want to tell us about</p> <p>13 9D?</p> <p>14 A. Mesh fibers are present, but the main</p> <p>15 finding is the blueness of the collagen.</p> <p>16 Q. Do you see any traumatic neuromas?</p> <p>17 A. No.</p> <p>18 Q. Any ganglia?</p> <p>19 A. No.</p> <p>20 Q. Any thrombosed vessels?</p> <p>21 A. No.</p> <p>22 Q. Anything else of significance that you</p> <p>23 want to tell us about the photomicrograph 9D?</p> <p>24 A. No.</p> <p>25 Q. 9E.</p>
<p style="text-align: right;">Page 43</p> <p>1 capillaries in here.</p> <p>2 Q. Good capillaries -- are you saying you</p> <p>3 don't see any capillaries in here?</p> <p>4 A. I don't see ones that I could label for</p> <p>5 you and say this is definitely a capillary.</p> <p>6 Q. Do you see any traumatic neuromas?</p> <p>7 A. No, I do not.</p> <p>8 Q. Do you see any ganglia?</p> <p>9 A. No, I do not.</p> <p>10 Q. Do you see any abnormal vessels?</p> <p>11 A. No, I don't believe that was part of my</p> <p>12 findings that I listed in my report.</p> <p>13 Q. Same questions on 9A and B regarding</p> <p>14 finding any neuromas, traumatic neuromas, ganglia,</p> <p>15 abnormal vessels?</p> <p>16 A. No.</p> <p>17 Q. All right. Anything else you want to tell</p> <p>18 us about photograph 9 -- your thumb is on it.</p> <p>19 A. 9C.</p> <p>20 Q. 9C.</p> <p>21 A. No.</p> <p>22 Q. All right. 9D.</p> <p>23 A. 9D is a trichrome stain which highlights</p> <p>24 areas of collagen deposition in blue. So that's</p> <p>25 what you would see in fibrosis and scar. So all of</p>	<p style="text-align: right;">Page 45</p> <p>1 A. 9E and 9F are both S100 stains which were</p> <p>2 performed to highlight the nerves present in the</p> <p>3 tissue. On low power 9E shows the distribution of</p> <p>4 these S100 positive nerve fibers and then 9F shows a</p> <p>5 higher power image of the nerve fibers.</p> <p>6 Q. Is there anything of significance on 9E</p> <p>7 that you are going to tell the jury about?</p> <p>8 MS. O'DELL: Objection to the form.</p> <p>9 THE WITNESS: So the nerve fibers are</p> <p>10 embedded in the scar tissue immediately around the</p> <p>11 mesh.</p> <p>12 BY MR. VOUDOURIS:</p> <p>13 Q. Could you draw for us the scar tissue?</p> <p>14 A. (Witness complies.)</p> <p>15 Q. And could you label that, please?</p> <p>16 A. (Witness complies.)</p> <p>17 Q. And circle, if you can, nerves that are in</p> <p>18 the scar tissue.</p> <p>19 A. The reason I have a higher power image is</p> <p>20 because it's hard to identify them definitively on</p> <p>21 low power, so I'm showing you two images to confirm</p> <p>22 their presence.</p> <p>23 Q. And you have no idea whether those nerves</p> <p>24 are motor or sensory, do you?</p> <p>25 A. No.</p>

<p style="text-align: right;">Page 46</p> <p>1 Q. Okay. 9E?</p> <p>2 MS. O'DELL: Were you finished?</p> <p>3 MR. VOUDOURIS: I'm sorry. I don't want</p> <p>4 to cut you off.</p> <p>5 THE WITNESS: I was going to say in a</p> <p>6 patient presenting with pain in this area, I would</p> <p>7 assume that some of these are sensory.</p> <p>8 BY MR. VOUDOURIS:</p> <p>9 Q. And the basis for that statement?</p> <p>10 A. The pain the patient is experiencing in</p> <p>11 the area. If I cut your finger and you're</p> <p>12 experiencing pain in the area, I'm going to guess</p> <p>13 you have some sensory nerves there that caused the</p> <p>14 pain.</p> <p>15 Q. And I'm sorry if I already asked this, but</p> <p>16 in your reference list I think that we had as</p> <p>17 Exhibit 4, are there any case-controlled studies</p> <p>18 comparing nerves contained in mesh scar tissue in</p> <p>19 women who do not complain of pain versus an</p> <p>20 assessment of nerves and scar tissue with women who</p> <p>21 do complain of pain after removal of a midurethral</p> <p>22 sling?</p> <p>23 A. Yes.</p> <p>24 Q. Which one?</p> <p>25 A. Hill. We discussed that one.</p>	<p style="text-align: right;">Page 48</p> <p>1 pain supports their clinical symptoms presentation.</p> <p>2 Q. And what about the appearance on histology</p> <p>3 that you believe supports your opinion?</p> <p>4 A. The extensive scarring, the presence of</p> <p>5 the nerves entrapped in the scar, and the physical</p> <p>6 presence of erosions in the area. That's what I'm</p> <p>7 linking together.</p> <p>8 Q. 9E. And I'm sorry, is there -- 9E, is</p> <p>9 there anything else you want to tell the jury about</p> <p>10 that is significant on 9E?</p> <p>11 A. No.</p> <p>12 Q. 9F?</p> <p>13 A. I have circled the higher power areas of</p> <p>14 nerves.</p> <p>15 Q. Do you have an opinion to a reasonable</p> <p>16 degree of medical certainty whether the nerves in 9E</p> <p>17 and 9F are motor or sensory?</p> <p>18 A. Some of them are likely -- more likely</p> <p>19 than not sensory.</p> <p>20 Q. Which ones?</p> <p>21 A. I cannot point to -- you cannot tell under</p> <p>22 histology which ones are. That's not something we</p> <p>23 can do.</p> <p>24 Q. What type of sensory-invoking nerves are</p> <p>25 these?</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Anything else?</p> <p>2 A. Pain perception can be complex. I'm only</p> <p>3 documenting that the nerves are present in the</p> <p>4 patients who are complaining of pain.</p> <p>5 Q. And I'm sorry if my question wasn't clear.</p> <p>6 We were talking about Exhibit 4. And the question</p> <p>7 was, could you point me to any case-controlled</p> <p>8 studies that compared nerves and scar tissue in</p> <p>9 women who did not have complaints of pain versus</p> <p>10 nerves and scar tissue with women who did complain</p> <p>11 of pain after excision of a midurethral sling?</p> <p>12 A. Yes.</p> <p>13 Q. You mentioned Hill. Is there anything</p> <p>14 else on Exhibit 4?</p> <p>15 A. Hill would be the best example of that, I</p> <p>16 believe.</p> <p>17 Q. Okay.</p> <p>18 A. That comes to mind.</p> <p>19 Q. Next.</p> <p>20 A. But I would mention that pain is -- we all</p> <p>21 know different people have different thresholds for</p> <p>22 pain. And that doesn't mean that you can't find</p> <p>23 similar findings in patients who experience pain.</p> <p>24 Pain is a complex clinical entity, but I think that</p> <p>25 the pathology in these patients who are experiencing</p>	<p style="text-align: right;">Page 49</p> <p>1 A. I don't know.</p> <p>2 Q. Okay. Anything else in Exhibit 9F that</p> <p>3 you find significant that you are going to tell the</p> <p>4 jury?</p> <p>5 A. No.</p> <p>6 Q. We marked your supplemental report as</p> <p>7 Exhibit 8?</p> <p>8 MS. O'DELL: You marked it as Exhibit 8.</p> <p>9 MR. VOUDOURIS: Is that correct?</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MR. VOUDOURIS:</p> <p>12 Q. As part of your review of these three</p> <p>13 Ethicon cases, including Ms. Barker, did you,</p> <p>14 yourself, do any experiments with a control group?</p> <p>15 A. No.</p> <p>16 Q. Do you know how this tissue was fixed</p> <p>17 after it was removed from Ms. Barker?</p> <p>18 A. In formalin.</p> <p>19 Q. What does formalin do to tissue?</p> <p>20 A. It hardens it, makes it easier to cut. It</p> <p>21 cross-links proteins and makes them better for</p> <p>22 processing in histology, the tissue better</p> <p>23 preserved.</p> <p>24 Q. Do you know if formalin has any effect on</p> <p>25 polypropylene?</p>

<p style="text-align: right;">Page 50</p> <p>1 A. Dr. Iakovlev did look at that question in 2 one of his studies. Would you like me to refer to 3 that one? 4 Q. I'm asking you, I'm sorry. 5 A. So I haven't performed experiments 6 personally. But there is literature available that 7 I relied on that used control groups looking at 8 polypropylene mesh exposed to formalin that had not 9 been implanted in patients and in ones that had been 10 implanted in patients. The longer they were 11 implanted in patients, the more degradation they 12 saw. They did not see degradation in the ones that 13 had sat in formalin for up to, I think, four months. 14 Q. And those case-controlled studies would be 15 contained in Exhibit 4? 16 A. They are Iakovlev, the most recent one, 17 2005, I believe. Would you like me to -- 18 Q. 2005? 19 A. 2015. 20 Q. Yes, please tell us the one that you are 21 referring to. 22 A. Oh, yeah. Let's see. 23 Q. Just -- can you tell us the title of the 24 article? 25 A. I just want to confirm because there are</p>	<p style="text-align: right;">Page 52</p> <p>1 Scott Guelcher, G-U-E-L-C-H-E-R, and 2 Robert Bendavid. There are multiple institutions. 3 BY MR. VOUDOURIS: 4 Q. Any article in your reference list other 5 than that one? 6 A. I don't think so. I think that was a nice 7 case-controlled study looking at the effects of 8 formalin on mesh. 9 Q. What is Xylene? 10 A. What is Xylene? 11 Q. Yes. 12 A. It's another preservative and used in 13 tissue processing as well. 14 Q. Do you know if it was used in the tissue 15 processing in Ms. Barker? 16 A. I don't know. 17 Q. How about in Ms. Thompson or Ms. Phelps? 18 A. I don't know. 19 Q. What does Xylene do to polypropylene? 20 A. I don't know. 21 Q. Have you ever treated women who have had a 22 midurethral sling implanted for erosion? 23 A. I am a pathologist, so I don't treat 24 patients. 25 Q. Same question for urinary dysfunction?</p>
<p style="text-align: right;">Page 51</p> <p>1 several articles here which one it is so I'm not 2 giving you the wrong testing of pristine mesh. 3 Up to four months of formalin exposure and 4 there was no detectable degradation. So this is the 5 study and it was published in 2015. 6 Q. Could you -- 7 A. Title is Degradation of Polypropylene 8 In Vivo, a Microscopic Analysis of Meshes Explanted 9 From Patients. 10 Q. Anyone else other than Dr. Iakovlev that 11 you're relying upon for that statement? 12 A. I don't believe that there is other 13 literature to the contrary, looking at the specific 14 finding of the tree barking. 15 Q. That wasn't my question. 16 A. Your question is are there other articles 17 that I looked at? 18 MR. VOUDOURIS: Can you read it back, 19 please? 20 (Whereupon, the reporter read the record 21 as follows: 22 "Question: Anyone else other than 23 Dr. Iakovlev that you're relying upon for that 24 statement?") 25 THE WITNESS: I guess his coauthors,</p>	<p style="text-align: right;">Page 53</p> <p>1 A. I'm a pathologist. I don't treat 2 patients. 3 Q. Same for pelvic pain? 4 A. I am a pathologist. I don't treat 5 patients. 6 Q. Same for dyspareunia? 7 A. Same answer. 8 Q. I also imagine you don't have any opinions 9 on when a midurethral sling should be revised 10 because you don't perform the surgery, correct? 11 A. True, I don't perform the surgery. 12 Q. Exhibit 10, please. 13 A. Exhibit 10 is the surgical pathology 14 report. 15 Q. Right. 16 A. For Ms. Barker. 17 Q. Does the pathologist comment on any mesh 18 degradation? 19 A. No, they did a gross exam only, which is 20 common in some pathology labs. 21 Q. Did this pathologist mention tree barking? 22 A. They didn't do a microscopic examination 23 so they could not have commented on tree barking. 24 Q. So the answer to my question is no? 25 A. Correct.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q. Did this pathologist document anything 2 about mesh shrinkage? 3 A. No, they were documenting that the mesh 4 material was removed. 5 Q. Did this pathologist document anything 6 about mesh contracture? 7 A. No. 8 Q. Did this pathologist document anything 9 about mesh roping? 10 A. No, that wouldn't be standard. 11 Q. And how about curling? 12 A. No, it would not be standard. 13 Q. And how about fraying? 14 A. No. 15 Q. Did this pathologist do any type of 16 clinical pathologic diagnosis? 17 A. They did a gross diagnosis only. 18 Q. So the answer to my question is no, 19 correct? 20 MS. O'DELL: She answered your question. 21 THE WITNESS: Well, the clinical 22 pathologic correlation that they did was 23 confirmation that it was a GU device that was 24 removed, basically. 25</p>	<p style="text-align: right;">Page 56</p> <p>1 under the light microscope? 2 A. Yes. 3 Q. Did you measure the tree barking thickness 4 in any of your photographs? 5 A. No. 6 Q. Do you have any idea what the thickness 7 is? 8 A. I did not measure them. 9 Q. Do you believe it's all -- that they are 10 five microns or less? 11 A. Likely. 12 Q. Handing you what is marked as Defense 13 Exhibit 5. Can you identify that again for us, 14 please? 15 A. This is the spreadsheet used to summarize 16 my findings. 17 Q. And this is a spreadsheet that you 18 created? 19 A. Yes. 20 Q. And have we discussed all the findings for 21 Daphne Barker that you have on this spreadsheet? 22 A. I believe we have when we reviewed the 23 images. 24 Q. Did you do any testing of the mesh that 25 was explanted from Ms. Barker last month?</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. VOUDOURIS: 2 Q. That's it, correct? 3 A. Yeah. 4 MR. VOUDOURIS: Can we go off the record 5 for a minute. 6 (Whereupon, a brief recess was taken.) 7 BY MR. VOUDOURIS: 8 Q. Dr. Allison, did you ever examine 9 Ms. Barker? 10 A. No. 11 Q. Did you ever speak to any of her 12 physicians? 13 A. No. 14 Q. Have you read any depositions in this 15 case? 16 A. No. 17 Q. Have you consulted with any other health 18 care professional in your review of the Barker case? 19 A. No. 20 Q. Did you consult with any health care 21 professional in your review of either the Phelps or 22 the Thompson case? 23 A. No. 24 Q. Is the extent of your review in this case, 25 when it comes to the pathology, reviewing the slides</p>	<p style="text-align: right;">Page 57</p> <p>1 A. No, I did not. 2 Q. Are you relying on anyone's opinions 3 regarding an inspection for analysis of that 4 explanted mesh for your opinions in this case? 5 A. I have the gross examination report from 6 the person who grossed the case. 7 Q. But other than that, no? 8 A. No. 9 Q. Dr. Allison, those are all the questions I 10 have for now. I may have a few follow-up questions 11 after redirect by counsel. 12 A. Okay. 13 MR. VOUDOURIS: What one are you looking 14 for? 15 MS. O'DELL: I'm looking for Exhibit 10. 16 THE WITNESS: This one? 17 MS. O'DELL: I'm sorry, Exhibit 8. 18 EXAMINATION 19 BY MS. O'DELL: 20 Q. Dr. Allison, Exhibit 8 is your 21 supplemental report in the Barker case, correct? 22 A. Correct. 23 Q. And looking at page one, is there a typo 24 regarding the date of Ms. Barker's implant in -- or 25 excuse me, explant surgery on the first page of your</p>

<p style="text-align: right;">Page 58</p> <p>1 report?</p> <p>2 A. Yes, there is. I noticed that this</p> <p>3 morning.</p> <p>4 Q. Okay. And describe what the typo is.</p> <p>5 A. So the date of the partial excision of the</p> <p>6 TVT midurethral sling is -- the year is incorrect.</p> <p>7 So February 12, 2012, should read</p> <p>8 February 12, 2016. I mean, that's documented in the</p> <p>9 pathology report and obviously occurred after she</p> <p>10 presented in December 29, 2015.</p> <p>11 Q. Okay. Would you mind just correcting that</p> <p>12 on the exhibit, please?</p> <p>13 A. (Witness complies.)</p> <p>14 MR. VOUDOURIS: You probably just want to</p> <p>15 put your initials next to that.</p> <p>16 MS. O'DELL: I have nothing further.</p> <p>17 MR. VOUDOURIS: One follow-up question</p> <p>18 regarding your report, which is Exhibit 8.</p> <p>19 THE WITNESS: Yes.</p> <p>20 EXAMINATION</p> <p>21 BY MR. VOUDOURIS:</p> <p>22 Q. The paragraph that starts with "My job."</p> <p>23 A. Okay.</p> <p>24 Q. Do you have a sentence there that says,</p> <p>25 "Other physicians rely on me to diagnose the cause</p>	<p style="text-align: right;">Page 60</p> <p>1 MR. VOUDOURIS: And do you plan to appear</p> <p>2 live at trial in this case?</p> <p>3 THE WITNESS: If necessary.</p> <p>4 MR. VOUDOURIS: Now we're done. Thank</p> <p>5 you.</p> <p>6 (Whereupon, the deposition was concluded</p> <p>7 at 10:33 a.m.)</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>
<p style="text-align: right;">Page 59</p> <p>1 of their patient's problems," correct?</p> <p>2 A. Yes.</p> <p>3 Q. Does any physician at Stanford rely upon</p> <p>4 you to diagnose clinical sequelae from explanted</p> <p>5 midurethral meshes?</p> <p>6 A. No, not currently.</p> <p>7 Q. Has any surgeon relied upon you to</p> <p>8 diagnose the cause of sequelae from explanted</p> <p>9 midurethral meshes?</p> <p>10 A. No, the surgeons are removing them because</p> <p>11 they have made their own clinical judgment that they</p> <p>12 need to be removed because the symptoms they are</p> <p>13 causing.</p> <p>14 Q. And you are not a surgeon, correct, who</p> <p>15 implants or explants these?</p> <p>16 A. No, I simply describe the findings that</p> <p>17 are linked to those in my pathology report.</p> <p>18 MR. VOUDOURIS: Those are all the</p> <p>19 questions I have unless there is further direct.</p> <p>20 MS. O'DELL: I have nothing further.</p> <p>21 MR. VOUDOURIS: All right. We're done.</p> <p>22 (Whereupon, a brief recess was taken.)</p> <p>23 MR. VOUDOURIS: Are you having her read</p> <p>24 any of these transcripts?</p> <p>25 MS. O'DELL: She will read and sign.</p>	<p style="text-align: right;">Page 61</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition over carefully</p> <p>4 and make any necessary corrections. You should</p> <p>5 state the reason in the appropriate space on the</p> <p>6 errata sheet for any corrections that are made.</p> <p>7 After doing so, please sign the errata</p> <p>8 sheet and date it.</p> <p>9 You are signing same subject to the</p> <p>10 changes you have noted on the errata sheet, which</p> <p>11 will be attached to your deposition.</p> <p>12 It is imperative that you return the</p> <p>13 original errata sheet to the deposing attorney</p> <p>14 within thirty (30) days of receipt of the deposition</p> <p>15 transcript by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be accurate</p> <p>17 and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

Kimberly H. Allison, M.D.

<p style="text-align: right;">Page 62</p> <p>1 ERRATA SHEET</p> <p>2</p> <p>3 PAGE LINE CHANGE</p> <p>4 _____</p> <p>5 REASON: _____</p> <p>6 PAGE LINE CHANGE</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 PAGE LINE CHANGE</p> <p>10 _____</p> <p>11 REASON: _____</p> <p>12 PAGE LINE CHANGE</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 PAGE LINE CHANGE</p> <p>16 _____</p> <p>17 REASON: _____</p> <p>18 PAGE LINE CHANGE</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 PAGE LINE CHANGE</p> <p>22 _____</p> <p>23 REASON: _____</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 64</p> <p>1 STATE OF CALIFORNIA)</p> <p>2 COUNTY OF YOLO)</p> <p>3 I, ELAINA BULDA-JONES, a Certified Shorthand</p> <p>4 Reporter of the State of California, duly authorized</p> <p>5 to administer oaths pursuant to Section 2025 of the</p> <p>6 California Code of Civil Procedure, do hereby</p> <p>7 certify that</p> <p>8 KIMBERLY H. ALLISON, M.D.,</p> <p>9 the witness in the foregoing deposition, was by me</p> <p>10 duly sworn to testify the truth, the whole truth and</p> <p>11 nothing but the truth in the within-entitled cause;</p> <p>12 that said testimony of said witness was reported by</p> <p>13 me, a disinterested person, and was thereafter</p> <p>14 transcribed under my direction into typewriting and</p> <p>15 is a true and correct transcription of said</p> <p>16 proceedings.</p> <p>17 I further certify that I am not of counsel or</p> <p>18 attorney for either or any of the parties in the</p> <p>19 foregoing deposition and caption named, nor in any</p> <p>20 way interested in the outcome of the cause named in</p> <p>21 said deposition dated the _____ day of</p> <p>22 _____, 2016.</p> <p>23</p> <p>24</p> <p>25 ELAINA BULDA-JONES, RPR, CSR 11720</p>
<p style="text-align: right;">Page 63</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3</p> <p>4</p> <p>5 I, _____, do hereby certify</p> <p>6 that I have read the foregoing pages, and that the</p> <p>7 same is a correct transcription of the answers given</p> <p>8 by me to the questions therein propounded, except</p> <p>9 for the corrections or changes in form or substance,</p> <p>10 if any, noted in the attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13 _____</p> <p>14 KIMBERLY H. ALLISON, M.D. DATE</p> <p>15</p> <p>16</p> <p>17</p> <p>18 Subscribed and sworn</p> <p>19 to before me this</p> <p>20 _____ day of _____, 20____.</p> <p>21 My commission expires: _____</p> <p>22</p> <p>23 _____</p> <p>24 Notary Public</p> <p>25</p>	